REMARKS

By this amendment the applicants have herein amended claims 1 and 27, added new claim 36, and canceled claims 17 - 26. The following remarks are responsive to the Office Action with a mail date of June 7, 2007 and corrects and replaces the applicants' response sent on September 7, 2007

A. Withdrawal of newly submitted claims 27-35

The Office has constructively withdrawn the applicants' claim submitted with the filing of their RCE application as being directed to a non-elected invention.

The applicants, strongly traverse this action by the Office in that the applicants have consistently and continuously taken the position with the Office that the phrase "human milk supplement" is a recognized term of art that one of ordinary skill in the art would understand. The Office, on the other hand, has not met its burden of identifying the skill level of one of ordinary skill in the art and has repeatedly countered that "human milk supplement" has no bearing on the applicants' claims. The withdrawal of claims from consideration by the Office points to the deficiency in the Office's stated position. First and foremost, the original method claims submitted by the applicants were notdirected to direct feeding of the "human milk supplement" to a pre-term infant. Those claims (original claims 13 & 14) were drawn to a "method of feeding a pre-term infant comprising administering to said infant the supplement of" claims 1 and 10. Both claims 1 and 10 contained the phrase "human milk supplement". As such, one of ordinary skill in the art would know and understand that the "supplement" referenced in the method claims of claims 13 and 14 was a "human milk supplement" and that "supplement" would, therefore, have to be mixed with human breast milk because a "human milk supplement", by itself is not nutritionally complete. Direct feeding of a "human milk supplement" to a pre-term infant would put that infant at risk, and one of ordinary skill in the art would know that.

Withdrawal of the "constructive election" of applicants' claims 27-35 for consideration is respectfully requested.

B. Rejection of claims 17-26 under 35 U.S.C. § 112, second paragraph and 35 U.S.C. § 101

The applicants have herein canceled claims 17-26 that the Examiner rejected under 35 U.S.C. § 112, second paragraph and 35 U.S.C. § 101.

C. Rejection of Claims 1-8 under 35 U.S.C. § 102(b).

The Examiner has rejected claims 1-8 "as being anticipated by Pellico (5,817,695) ..." in that "Pellico discloses a nutritional composition comprising 2-15% carbohydrate, 40-80%, and 100% protein." [sic]

The applicants respectfully traverse this ground for rejection in that Pellico discloses and teaches an "elemental nutritional product for cancer patients" (Pellico, claim 1) wherein the amino acids (the protein component) are imbalanced (abstract and claims). As such, Pellico is non-analogous art and one of ordinary skill in the art would not consider his teaching in formulating a human milk supplement. The nutritional requirements of an infant in need of a human milk supplement are very different than those of a cancer patient.

The Examiner has also rejected claims 1-2, 6, 9, 13, 15-18, 22, and 25, under new grounds as being anticipated by EP 0 953 289 ("EP") under 35 U.S.C. § 102(b).

The applicants respectfully traverse this ground for rejection in that as with Pellico the teaching of EP are non-analogous art in that EP teach a milk replacement replacer. Not only is a human milk supplement not a milk replacement the protein component as taught by EP is not "a protein component suitable for infant consumption selected from the group consisting of intact milk protein isolate, hydrolyzed whey protein isolate and combinations thereof." EP teach that their preferred protein source is soy protein isolate or casein, paragraphs [0015] and [0016]. In addition the "[v]arious other natural or synthetic proteins and peptides" taught and suggested by EP, paragraph [0017], are low grade proteins and not proteins "suitable for infant consumption selected from the group consisting of intact milk protein isolate, hydrolyzed whey protein isolate and combinations thereof."

D. Rejection of claims under 35 U.S.C. § 103(a)

The Examiner has rejected claims 15 and 16 under 35 U.S.C. § 103(a) as being unpatentable over Pellico.

As argued above, Pellico teaches using a protein component that is unbalanced for amino acids. As such the applicants respectfully traverse the grounds for this rejection as liquid or dry compositions cannot over come the deficiency of Pellico to make this reference relevant.

The Examiner has also rejected claims 1-9, 12-13, and 15-26 under 35 U.S.C. § 103(a) as being unpatentable over US 6,294,206 B1 to Barrett-Reis *et al.* in that the "upper limit for fat (30%) and the lower limit for carbohydrate (15%) in the reference are closer to instant lower and upper limit of fat and carbohydrate respectively and the term 'about' taught by reference is suggestively of some flexibility. Therefore one of ordinary skill in the art would be motivated to vary the amounts taught by reference to obtain the best possible results."

The applicants respectfully traverse this ground for rejection. First, the mere fact that a reference states that its teaching is a "general guideline" (Barrett-Reis, column 6, lines 42-43) and the stated ranges contain the word "about" does not mean that someone of ordinary skill in the art, without access to the applicants' disclosure and teachings, would be motivated to vary

the amounts of carbohydrates and fats taught in Barrett-Reis below or above the stated limits in the reference. This is especially true because the preferred amounts disclosed in Barrett-Reis teach one of ordinary skill in the art that any modifications should occur within the stated ranges, not outside of them. The applicants take note that the Examiner takes issue with the use by the applicants of the word "should" in defining the teachings of Barrett-Reis, but without the use of hind-sight in light of the applicants' teaching, there is no reason or motivation for one of ordinary skill in the art to venture beyond the stated ranges by more than 8% on the lower limit for carbohydrates and by more than 17% on the upper limit for fat. The mere absence of a teaching not to vary the taught ranges does not transform the teaching into a suggestion 'to' vary the amounts. Under the reasoning that the Office seems to be espousing, no claim for a human milk supplement could ever be found patentable over Barrett-Reis because the reference is a "general guideline" and therefore any modification beyond the taught ranges would still be within the scope of the teaching of Barrett-Reis. Since the applicants to do not seriously believe the Examiner is espousing such a position they do wonder at what point outside of the ranges disclosed by Barrett-Reis the Office believes is not within the teachings of Barrett-Reis. Applicants believe that 8% and 17% variances from the ranges taught by Barrett-Reis are not insignificant changes and as such, fall outside such teachings, and a finding of the level of ordinary skill would be in order.

Claims 1-9 and 12-13 are also reject under 35 U.S.C. § 103(a) as being unpatentable over US 6,294,206 B1, Barrett-Reis *et al.* in view of Neylan *et al.* US Patent 5,340,603.

As mentioned above, without the use of hindsight, Barrett-Reis does not teach the claimed ranges of applicants' claimed ingredients.

The Neylan *et al.* reference does not correct the deficiency. In fact, Neylan *et al.* cannot suggest the applicants' ranges because Neylan *et al.* teach an infant formula, not a human milk supplement. An infant formula is designed to be a replacement for or a supplement to the feeding of human breast milk. An infant formula is not designed to be a "human milk supplement" and therefore mixed with human milk prior to being consumed, as a human milk supplement is.

Lastly, Neylan *et al.*, alone, or in combination with Barrett-Reis, do not teach the instant claimed ranges. As mentioned above, Barrett-Reis, teach higher carbohydrate and lower fat levels than the applicants' claim as their invention. Neylan *et al.*, on the other hand, teach lower protein and higher carbohydrate levels than the applicants' claimed invention (See Applicants' Table 3, page 8). It is unclear to the applicants' how these two references would or could suggest or teach their invention to one of ordinary skill in the art as neither reference teaches their claimed carbohydrate level.

The Office has stated that Neylan *et al.* is cited for its rationale for reducing levels of carbohydrate to reduce carbon dioxide production in an infant. This argument fails on may levels. First, Neylan *et al.* teach the manipulation of carbohydrate levels in an infant formula to